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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/748,412 | 12/21/2000 | Wouter E. Roorda | 50623.26 | 3752 |

7590 01/30/2003

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EXAMINER

PHAN, HIEU

ART UNIT PAPER NUMBER

3738

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

NK

Office Action Summary

Application No.

09/748,412

Applicant(s)

ROORDA, WOUTER E.

Examiner

Hieu Phan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

1-4, 8, 10, 12-14 and 16-23
1-4, 10, 12 and 18-20

- 4) ☒ Claim(s) 8, 10, 12-14 and 16-23 is/are pending in the application.
- 4a) Of the above claim(s) 8, 13, 14, 16, 17 and 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 10, 12 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

Drawings

1. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81. No new matter may be introduced in the required drawing.

Response to Election/Restriction

2. Applicant's election without traverse of Group I, Specie I, claims 1-4, 10, 12 and 18-20, in Paper No. 6 is acknowledged. Non-elected claims 8, 13, 14, 16, 17 and 21-23 have been withdrawn from consideration.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4, 10, 12, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fearnot et al. (U.S. Patent 5,609,629).

Fearnot et al. disclosed a porous stent (10) with a coatings (16, 18, 20, 22 and 24) containing anti-thrombotic and anti-inflammatory agents (Abstract, column 2 lines 66 and 67, column 3 lines 1-16 and 30-67, column 4 lines 23-39

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and 48-61, column 5 lines 12-47, column 7 lines 5-22 and 30-47, column 8 lines 46-67, column 9 lines 1-26 and column 12 lines 39-41).

Fearnot et al. does not disclose expressly a coating including a first region having a component for reducing or preventing the formation of thrombi and a second region having a component for reducing or preventing infiltration of macrophages in the thrombi, wherein the second region of the coating is positioned beneath the first region.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have a stent with a first region having a component for reducing or preventing the formation of thrombi and a second region having a component for reducing or preventing infiltration of macrophages in the thrombi, wherein the second region of the coating is positioned beneath the first region because Applicant has not disclosed that a stent with a first region having a component for reducing or preventing the formation of thrombi and a second region having a component for reducing or preventing infiltration of macrophages in the thrombi, wherein the second region of the coating is positioned beneath the first region provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the first coating in the first region position beneath the second region because

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the bioactive materials in the first and second regions would prevent inflammatory and thrombi.

Therefore, it would have been an obvious matter of design choice to modify Fearnot et al. to obtain the invention as specified in claims 1-4, 10, 12, 18 and 19.

5. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fearnot et al. (U.S. Patent 5,609,629) in view of Kunz et al. (U.S. Patent 5,981,568).

Fearnot et al. is explained as before. But Fearnot et al. fail to disclose the coating is made from the material comprising PTFE.

Kunz et al. teach inhibiting growth of vascular smooth muscle cells using an intravascular stent with a PTFE coating containing therapeutic agent (column 30 lines 1-12). The advantages of using the PTFE as the material for coating a stent are PTFE is biocompatible and it is porous, which allows the therapeutic agent to be release from the PTFE material.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the teaching of Kunz et al.. to modify the apparatus Fearnot et al. to have the coating made from the material comprising PTFE. The motivations for incorporating the feature of Kunz et al.. into the apparatus of Fearnot et al. are PTFE is biocompatible and it is porous, which allows the therapeutic agent to be release from the PTFE material.

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Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hieu Phan whose telephone number is 703-308-8969.

The examiner can normally be reached on Monday-Friday from 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.

Hieu Phan
Examiner
Art Unit 3738



**CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700**